

Food and Drug Administration, HHS

§ 178.3870

(d) The substances and optional adjunct substances employed in the production of or added to reinforced wax include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction for use in reinforced wax and used in accordance with such sanction or approval.

(3) Substances identified in this subparagraph and subject to any limitations provided therein:

List of substances	Limitations
Copolymer of isobutylene modified with isoprene. Petroleum wax, Type I and Type II. Polyethylene. Rosins and rosin derivatives as provided in § 178.3870. Synthetic wax polymer as described in § 176.170(a)(5) of this chapter.	Not to exceed 5 percent by weight of the petroleum wax.

(e) Reinforced wax conforming with the specifications in this paragraph is

List of substances	Limitations
Erucamide (erucylamide). Formaldehyde, polymer with 1-naphthalenol (CAS Reg. No. 25359-91-5).	For use only as an antiscaling or release agent, applied on the internal parts of reactors employed in the production of polyvinyl chloride and acrylic copolymers, provided that the residual levels of the additive in the polymer do not exceed 4 parts per million.
<i>N,N'</i> -Dioleylethylenediamine	For use only in polyvinyl chloride films in amounts such that the concentration of the substance in these films in the form in which the films contact food shall not exceed 0.055 milligram of the substance per square inch of film.
Oleoyl palmitamide. Polybutene, hydrogenated; complying with the identity prescribed under § 178.3740(b). Poly(vinyl acetate/vinyl <i>N</i> -octadecylcarbamate) (CAS Reg. No. 70892-21-6) produced by the reaction between stoichiometrically equivalent amounts of octadecyl isocyanate and vinyl alcohol/vinyl acetate copolymer; minimum average molecular weight is 500,000.	For use only subject to the limitations prescribed for hydrogenated polybutene under § 178.3740(b). For use only in application to the backing of pressuresensitive adhesive tapes at levels not to exceed 0.2 milligram per square centimeter (1.29 milligrams per square inch) of backing.
Rice bran wax	For use only in plastics intended for contact with dry foods identified as Type VIII in table 1 of § 176.170(c) of this chapter, at levels not in excess of 1.0 percent by weight of the polymer.
Saturated fatty acid amides manufactured from fatty acids derived from animal, marine, or vegetable fats and oils. Stearyl erucamide.	

[42 FR 14609, Mar. 15, 1977, as amended at 44 FR 69649, Dec. 4, 1979; 46 FR 51902, Oct. 23, 1981; 61 FR 25396, May 21, 1996; 61 FR 42381, Aug. 15, 1996]

used as provided in paragraph (e)(2) of this section.

(1) The chloroform-soluble portion of the water extract obtained by exposing reinforced wax to demineralized water at 70 °F for 48 hours shall not exceed 0.5 milligram per square inch of food-contact surface.

(2) It is used as a packaging material or component of packaging materials for cheese and cheese products.

[42 FR 14609, Mar. 15, 1977, as amended at 47 FR 1288, Jan. 12, 1982]

§ 178.3860 Release agents.

Substances listed in paragraph (b) of this section may be safely used as release agents in petroleum wax complying with § 178.3710 and in polymeric resins that contact food, subject to the provisions of this section.

(a) The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect or any limitations prescribed in this section.

(b) Release agents:

§ 178.3870 Rosins and rosin derivatives.

The rosins and rosin derivatives identified in paragraph (a) of this section

may safely be used in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or